

Message Text

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PAGE 01 STATE 180417
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-07 EB-08 COME-00 SNM-02
DEAE-00 TRSE-00 NSC-05 /038 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: RBUHRICH, M.D.
EA/IMS:ADORNHEIM (INFO)

-----038211 020407Z /17

R 020110Z AUG 77
FM SECSTATE WASHDC
TO AMEMBASSY JAKARTA

UNCLAS STATE 180417

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, ID

SUBJECT: FOOD AND DRUG ADMINISTRATION INSPECTION

REF: JAKARTA 9772
STATE 145345

1. FDA RECOMMENDS THAT, SINCE CONSULTANT TO P.T. KIMIA FARMA WILL VISIT FIRM IN AUGUST, INSPECTION SHOULD BE DEFERRED UNTIL LATER IN YEAR. THIS WILL ENABLE FIRM TO REMEDY ANY DEFICIENCIES CONSULTANT MAY OBSERVE.
2. FDA ANTICIPATES INSPECTIONS IN FAR EAST (JAPAN) IN DECEMBER 1977. INSPECTION OF P.T. KIMIA FARMA COULD EASILY BE MADE AT THAT TIME.
3. IT IS ALSO SUGGEST THAT FIRM SUBMIT A DRUG MASTER FILE (DMF) TO FDA IF THEY DO NOT PRESENTLY HAVE ONE. DRAFT COPY OF PROPOSED GUIDELINE FOR SUBMISSION OF DMF ARE BEING AIR UNCLASSIFIED

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PAGE 02 STATE 180417

MAILED TO EMBASSY FOR USE BY FIRM.

4. ANY QUESTIONS FIRM MAY HAVE RELATIVE TO THIS SUBJECT SHOULD BE DIRECTED TO:

U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF INTERNATIONAL AFFAIRS (HFC-40)

5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857
CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD INSPECTION, DRUGS, FOODS, VISITS, CONSULTANTS
Control Number: n/a
Copy: SINGLE
Sent Date: 02-Aug-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE180417
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770275-1194
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197708105/aaaadltz.tel
Line Count: 65
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: c5d69e4f-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 JAKARTA 9772
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1417236
Secure: OPEN
Status: NATIVE
Subject: FOOD AND DRUG ADMINISTRATION INSPECTION
TAGS: OGEN, ETRD, TBIO, ID, PT KIMIA FARMA
To: JAKARTA
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/c5d69e4f-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
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22 May 2009
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